EXHIBIT I

RANBAXY

RANBAXY LABORATORIES LTD, 95 PARK LANE, MAYFAIR, LONDON W1K 7TL. PHONE: (44 (0)20 7409 4510 FAX: (44 (0)20 7491 0561

PLEASE NOTE: RANBAXY LABORATORIES LIMITED has moved to:
20 Balderton Street, London, W1K 6TL, Tel: (44(0)20 7409 0075 Fax: (44 (0)20 7491 0561

28 February 2006

FAO: Büttner, U
European Patent Office
Erhardstrasse 27
D-80331 MUNICH
Germany

Our ref: RLL-200EP/P0049EP/SPG

Dear Sirs,

Re: **European Patent Application No. 01954256.2**
Oral Formulation Comprising Biguanide and an Organic Acid
In the name of Ranbaxy Signature LLC

I refer to your letter dated 15 April 2005, being a communication under Article 96(2) EPC.

In the first instance, the applicants would wish to submit a revised set of claims herewith. In addition, we are also enclosing a copy of the claims as currently on file, with the amendments tracked.

Now taking each of the Examiner's points in order;

Re: Item 1, Claims 1-7, 20-35, 37-45 (in part), 46-50

1) The Examiner's comments are noted.

2) In view of the Examiner's comments regarding lack of unity under Article 82 EPC, in the revised claims enclosed herewith claim 1 as currently on file has been deleted and claim 8 as currently on file has been amended to be the main claim. All subsequent composition claims have now been made dependent upon revised claim 1. Thus, we trust that the Article 82 EPC objection should now be waived.

RANBAXY

RANBAXY LABORATORIES LTD, 95 PARK LANE, MAYFAIR, LONDON W1K 7TF PHONE: +44 (0)20 7409 4510 FAX: +44 (0)20 7491 0561

3) Since claim 1 as currently on file has been deleted, we would expect that the Examiner's objection under Article 123(2) EPC should also now be waived.

4) The Examiner's comments are noted, but in the light of the amendments offered herein, the applicants do not believe that further comment is necessary.

5) The Examiner's comments here are noted.

Re: Item 2, Claims 8-19, 36, 37-43 (in part), 44, 45

6) It is noted that the Examining Division now raises an inventive step objection under Article 56 EPC. However, first it is presumed, from the comments made in the Office Action dated 2 March 2004 (and not retracted) that the Examining Division does find the subjected matter of original claim 8 (new claim 1) to be novel.

The Examiner alleges that the subject matter of claim 8 (new claim 1) differs from D1 only on the addition of hydroxymethylcellulose and a polyhydroxy alcohol. However, the Examiner ignores the teaching of D1 as to the amount of sweetener present. It can be seen from the Examples in D1 that the amount of sweetener present in the liquid formulations is considerably less in the prior art of D1 than that of the present invention.

In revised claim 1 enclosed herewith it is defined that;

> "said sweetener being present in amounts ranging from about 40% to about 80% by weight".

This contrasts with the Examples of D1 for the liquid formulations which use the following amounts of sweetener:

Example No.	% Sweetener
Example 1	0.3%
Example 2	1%
Example 3	0.3%
Example 4	10.25%
Example 5	6.2%
Example 6	10.03%
Example 7	0.28%

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Therefore, the teaching of D1 is to use (relatively) low amounts of sweetener, perhaps up to as high as 10%. Starting from D1, it might be considered to be obvious to use higher amounts, perhaps up to 15% or 20%. But it cannot be considered obvious to use amounts of sweetener which may be as high as 80%.

Moreover, none of the abovementioned Examples 1 to 7 of D1 include any amount of an hydroxymethylcellulose and/or a polyhydroxy alcohol. Thus, even if there is considered to be a teaching from D1 to incorporate these excipients into the composition, there is certainly no teaching as to the amounts that should be present and definitely no teaching that the amounts present should be from 0.01% to 5% by weight of alkyl hydroxyethylcellulose and from 5% to 55% by weight of polyhydroxy alcohol i.e. the very specific limitations included in revised claim 1.

Essentially, given the limitation to the amounts present defined by new claim 1, the skilled person would take no teaching at all from D1.

It should be noted that the applicants reserve the right to file any divisional applications.

We would hope that this application is now in order for allowance. However, in the event that the Examiner maintains any objection, or introduces a new objection, then the applicants hereby request oral proceedings in this case.

We should be grateful if you would please acknowledge safe receipt of this communication by date stamping and returning the enclosed form 1037.

Yours faithfully

S P Gilholm
European Patent Attorney
GA49442

Enc. Revised Claims
Claims as currently on file with amendments tracked
EPO Form 1037 (with confirmation)

P0049EP\EPO(2).28.02.06